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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

UPSHER-SMITH LABORATORIES,
INC.

Plaintiff,
v.

AUXILIUM PHARMACEUTICALS,
INC. AND FCB I LLC,

Defendants.

Civil Action No. _____

**COMPLAINT FOR DECLARATORY
JUDGMENT**

(Filed Electronically)

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Upsher-Smith Laboratories, Inc., by and through its attorneys, brings this Complaint against Defendants Auxilium Pharmaceuticals, Inc. and FCB I LLC (collectively “Defendants”) as follows:

THE PARTIES

1. Plaintiff, Upsher-Smith Laboratories, Inc. (“USL”), is a corporation organized and existing under the laws of the State of Minnesota, maintaining a principal place of business at 6701 Evenstad Drive, Maple Grove, Minnesota 55369.

2. Upon information and belief, Defendant Auxilium Pharmaceuticals, Inc. (“Auxilium”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 40 Valley Stream Parkway, Malvern, Pennsylvania 19355. On information and belief, Auxilium contracts with DPT Laboratories Ltd. (“DPT”) to manufacture its product Testim®. Upon information and belief, Auxilium specifically instructed DPT to manufacture Testim at DPT’s Lakewood, New Jersey facility.

3. Upon information and belief, Defendant FCB I LLC (“FCB”) is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 1105 North Market Street, Suite 1300, Wilmington, Delaware 19801.

NATURE OF THE ACTION

4. This is a declaratory action seeking a declaration of non-infringement and/or invalidity of U.S. Patent Nos. 7,608,605 (“the ’605 patent”); 7,608,606 (“the ’606 patent”); 7,608,607 (“the ’607 patent”); 7,608,608 (“the ’608 patent”); 7,608,609 (“the ’609 patent”); 7,608,610 (“the ’610 patent”); 7,935,690 (“the ’690 patent”); and 8,063,029 (“the ’029 patent”). This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 21 U.S.C. § 355(j)(5)(C).

6. On information and belief, Defendants engage in business in New Jersey and in this District, and thus, purposefully availed itself of the privilege of doing business in the State of New Jersey and in this District, both generally and specifically, by marketing pharmaceutical products throughout the State of New Jersey, including but not limited to its Testim® product that Defendants allege is respectively protected by the patents at issues herein. On information and belief, Defendants have a regular and established place of business in New Jersey and are engaged in carrying on a substantial part of its ordinary business on a permanent basis by contracting with DPT to manufacture its Testim® product in DPT's Lakewood, New Jersey facility. This Court also has personal jurisdiction over the Defendants because Defendants have waived any objection to personal jurisdiction by filing suit in this District against Watson Laboratories, Inc. (NV), Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. (collectively "Watson") (Civ. Action No. 2:12-cv-03084-JLL-MAH) alleging infringement of the patents at issue herein, by Watson filing Abbreviated New Drug Application ("ANDA") No. 09-1073 seeking FDA approval for the commercial manufacture, use and sale of a 1% testosterone gel for topical administration. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and/or 1400 because the Defendants are, at a minimum, subject to the personal jurisdiction in this District.

FACTUAL BACKGROUND

7. Upon information and belief, Defendant Auxilium is a specialty biopharmaceutical company. Auxilium holds New Drug Application (“NDA”) No. 21-454 on Testim® brand 1% testosterone gel (“Testim®”) and is the exclusive distributor of Testim® in the United States.

8. Upon information and belief, Defendant FCB is a holding company and is the current assignee of the ’605 patent, the ’606 patent, the ’607 patent, the ’608 patent, the ’609 patent, the ’610 patent, the ’690 patent, and the ’029 patent (collectively “the later-listed patents”). Defendant FCB is also the current assignee of U.S. Patent No. 8,178,518 (“the ’518 patent”).

9. Upon information and belief, the patent applications which led to the later-listed patents are all continuations of the same patent application – U.S. Patent App. Ser. No. 10/473,724. (“the ’724 application). The ’724 application was filed on April 21, 2003 and led to U.S. Patent No. 7,320,968 (“the 968 patent”).

10. Upon information and belief, the ’605 patent was assigned from CPEX Pharmaceuticals Inc. (“CPEX”) to Defendant FCB on April 5, 2011. According to the face of the patent, the ’605 patent is titled “Pharmaceutical Composition” and issued on October 27, 2009. Upon information and belief, Auxilium is a licensee to the ’605 patent. A copy of the patent is attached as Exhibit A.

11. Upon information and belief, the ’606 patent was assigned from CPEX to Defendant FCB on April 5, 2011. According to the face of the patent, the ’606 patent is titled

“Pharmaceutical Composition” and issued on October 27, 2009. Upon information and belief, Auxilium is a licensee to the ’606 patent. A copy of the patent is attached as Exhibit B.

12. Upon information and belief, the ’607 patent was assigned from CPEX to Defendant FCB on April 5, 2011. According to the face to the patent, the ’607 patent is titled “Pharmaceutical Composition” and issued on October 27, 2009. Upon information and belief, Auxilium is a licensee to the ’607 patent. A copy of the patent is attached as Exhibit C.

13. Upon information and belief, the ’608 patent was assigned from CPEX to Defendant FCB on April 5, 2011. According to the face of the patent, the ’608 patent is titled “Pharmaceutical Composition” and issued on October 27, 2009. Upon information and belief, Auxilium is a licensee to the ’608 patent. A copy of the patent is attached as Exhibit D.

14. Upon information and belief, the ’609 patent was assigned from CPEX to Defendant FCB on April 5, 2011. According to the face of the patent, the ’609 patent is titled “Pharmaceutical Composition” and issued on October 27, 2009. Upon information and belief, Auxilium is a licensee to the ’609 patent. A copy of the patent is attached as Exhibit E.

15. Upon information and belief, the ’610 patent was assigned from CPEX to Defendant FCB on April 5, 2011. According to the face of the patent, the ’610 patent is titled “Pharmaceutical Composition” and issued on October 27, 2009. Upon information and belief, Auxilium is a licensee to the ’610 patent. A copy of the patent is attached as Exhibit F.

16. Upon information and belief, the patent application that led to the ’690 patent was assigned from CPEX to Defendant FCB on April 5, 2011. According to the face of the patent, the ’690 patent is titled “Pharmaceutical Composition” and issued on May 3, 2011. Upon

information and belief, Auxilium is a licensee to the '690 patent. A copy of the patent is attached as Exhibit G.

17. Upon information and belief, the patent application that led to the '029 patent was assigned from CPEX to Defendant FCB on April 5, 2011. According to the face of the patent, the '029 patent is titled "Pharmaceutical Composition" and issued on November 22, 2011. Upon information and belief, Auxilium is a licensee to the '029 patent. A copy of the patent is attached as Exhibit H.

18. Upon information and belief, pursuant to 21 U.S.C. § 355(b)(1), Auxilium listed the '968 patent as covering Testim® in the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations prior to October 22, 2008. Upon information and belief, Auxilium listed the later-listed patents, as well as the '518 patent, as covering Testim® on or after October 27, 2009.

19. In 2008, USL submitted an Abbreviated New Drug Application ("ANDA") No. 79-178 to the FDA to obtain approval to market a testosterone transdermal gel product in a 1% strength ("Testosterone Gel 1%") prior to the expiration of the '968 patent, and prior to the issuance of the later-listed patents. USL's ANDA No. 79-178 contains a certification, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification").

20. USL is pursuing FDA approval in order to market its Testosterone Gel 1% product prior to the expiration of the '968 patent and the later-listed patents.

21. USL, pursuant to 21 U.S.C. §355(j)(2)(B), provided written notice in 2008 to Auxilium and Bentley Pharmaceuticals, Inc. ("Bentley") that USL had submitted ANDA 79-178.

USL filed a Paragraph IV certification with the FDA, certifying that the claims of the '968 patent will not be infringed by the commercial manufacture, use or sale of the proposed drug product for which the ANDA was submitted. The written notice that USL provided Auxilium and Bentley stated that USL's commercial manufacture, use and sale of Testosterone Gel 1% would not infringe the '968 patent, and expressly stated that additional legal grounds and factual bases exist regarding the invalidity, unenforceability, and/or non-infringement of certain or all claims of the '968 patent. Upon information and belief, Bentley was CPEX predecessor-in-interest to the '968 patent.

22. After receiving notice from USL, on December 4, 2008, Auxilium and CPEX filed suit against USL in the District of Delaware asserting infringement of only the '968 patent. *Auxilium Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc.*, Civil Action No. 08-908-SLR ("the Delaware action"). No other patents are currently asserted in the Delaware action.

23. On information and belief, after the Delaware action was commenced, Auxilium listed the later-listed patents in the Orange Book.

24. On or about April 2012, USL, pursuant to 21 U.S.C. §355(j)(2)(B), provided written notice to Auxilium and CPEX Pharmaceuticals, Inc. that USL supplemented its Paragraph IV certification for ANDA 79-178 with the FDA, certifying that the claims of the originally listed patent, the '968 patent, and the following later-listed patents—the '605 patent, the '606 patent, the '607 patent, the '608 patent, the '609 patent, the '610 patent, the '690 patent, and the '029 patent—will not be infringed by the commercial manufacture, use or sale of the proposed drug product for which the ANDA was submitted. The written notice that USL provided Auxilium and CPEX stated that USL's commercial manufacture, use and sale of

Testosterone Gel 1% would not infringe the '968 patent, and expressly stated that additional legal grounds and factual bases exist regarding the invalidity, unenforceability, and/or non-infringement of certain or all claims of these patents.

25. In Auxilium's SEC 10-Q filing for the quarterly period ending March 31, 2012, Auxilium announced that it "received a notice from Upsher-Smith in connection with its ANDA advising us and FCB of Upsher-Smith's Paragraph IV certification relating to the eight additional patents listed in the Orange Book in addition to the '968 patent-in-suit, and asserting that Upsher-Smith does not believe that the product for which it is seeking approval infringes any of the Orange Book listed Testim patents and that those patents are invalid."

26. On information and belief, on May 23, 2012, Auxilium and FCB filed suit in this District against Watson Laboratories, Inc. (NV), Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. (collectively "Watson") (Civ. Action No. 2:12-cv-03084-JLL-MAH) ("the Watson action"). Upon information and belief, in the Watson action, Auxilium and FCB asserted a claim for infringement of the '968 patent, the later-listed patents, and the '518 patent against Watson.

27. In a Press Release dated May 17, 2012 announcing the issuance of an additional patent Mr. Adrian Adams, Chief Executive Officer and President of Auxilium, stated, "We are very pleased that, in addition to the nine previously issued patents covering methods using Testim, the franchise is now further protected by a composition patent... This further strengthens our Testim patent estate which we intend to vigorously defend by pursuing all available legal and regulatory options in defense of Testim, including enforcement of all intellectual property rights and approved labeling."

28. Auxilium and FCB have demonstrated their intent to prevent generic competition to its Testim® product.

29. Auxilium has filed suit against USL, asserting the USL's proposed Testosterone Gel 1% infringes the related '968 patent.

30. Auxilium and FCB have shown their willingness to assert the later-listed patents and has already sued Watson in the District of New Jersey, asserting that Watson's proposed testosterone gel infringes the '968 patent and the later-listed patents. The later-listed patents are all continuations of the patent application that led to the '968 patent.

31. Auxilium and FCB have never disavowed intent to assert that USL's proposed Testosterone Gel 1% infringes the later-listed patents. To the contrary, Auxilium and FCB have not responded to USL's April 2012 letter and on information and belief, Auxilium has repeatedly told the public that it intends to vigorously defend Testim by pursuing all available legal and regulatory options, including enforcement of all intellectual property rights and approved labeling.

32. Because Auxilium has previously sued USL for infringement of its proposed Testosterone Gel 1% product on a related patent, because Auxilium and FCB have filed suit against Watson in this District for its proposed testosterone gel, and because Auxilium and FCB have not responded to USL's April 2012 letter, USL has a reasonable apprehension that Auxilium and FCB will sue USL for infringement of the later-listed patents with respect to USL's proposed Testosterone Gel 1% product.

33. To avoid legal uncertainty and to protect its substantial investment in its proposed Testosterone Gel 1% product, USL has brought these claims for declaratory judgment against the later-listed patents. An actual justiciable controversy exists between the parties as to the infringement and invalidity of the later-listed patents.

34. Due to the nature of the dispute, USL will seek to consolidate this action with Watson's action for the purpose of discovery and claim construction.

COUNT I

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 7,608,605

35. USL hereby restates and realleges the allegations set forth in Paragraphs 1-34 above and incorporates them by reference.

36. A case or controversy exists between USL and Defendants concerning the non-infringement of the '605 patent requiring a declaration of rights by this Court.

37. USL's submission of ANDA 79-178 for the purpose of obtaining approval to market its Testosterone Gel 1% product did not and does not infringe any valid and enforceable claim of the '605 patent under 35 U.S.C. §271(e)(2), nor would the manufacture, use, sale, offer of sale in and/or importation into the United States of USL's proposed Testosterone Gel 1% infringe any valid and enforceable claim of the '605 patent. USL's making, using, offering to sell, selling, and/or importing Testosterone Gel 1% does not and will not infringe, induce infringement or contribute to infringement by others of any claim of the '605 patent, even under the broadest reasonable construction of the claims of the '605 patent. USL cannot literally (either directly or contributorily) infringe any claim of the '605 patent because one of the components recited in each of the claim of the patent is entirely absent from USL's Testosterone Gel 1%. Moreover, USL cannot infringe (either directly or contributorily) under the doctrine of equivalents. Evidence in the specification and the statements made during prosecution demonstrate that the patentee recognized that the claimed invention's advancement over the prior art was the inclusion of the specific enhancer oxacyclohexadecan-2-one. The USL formulations are not within scope of the claimed invention, but instead, include only components found in the prior art acknowledged by the patentee during patent prosecution. If any claim of the '605 patent

were to be interpreted more broadly than this broadest construction, the claim would be invalid. As such, this count is amenable to summary judgment, even prior to a determination on claim construction.

38. USL is entitled to a declaration that the manufacture, use, sale, offer of sale and/or importation into the United States of the Testosterone Gel 1% product would not infringe any valid and enforceable claims of the '605 patent.

COUNT II

**DECLARATORY JUDGEMENT OF INVALIDITY
OF U.S. PATENT NO. 7,608,605**

39. USL hereby restates and realleges the allegations set forth in Paragraphs 1-38 above and incorporates them by reference.

40. The '605 patent is invalid for failure to meet one or more of the requirements of patentability under 35 U.S.C. §101, *et seq.*, including, but not limited to, 35 U.S.C. §§ 102 and 103.

41. USL is entitled to a declaratory judgment that the claims of the '605 patent are invalid.

COUNT III

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 7,608,606**

42. USL hereby restates and realleges the allegations set forth in Paragraphs 1-41 above and incorporates them by reference.

43. A case or controversy exists between USL and Defendants concerning the non-infringement of the '606 patent requiring a declaration of rights by this Court.

44. USL's submission of ANDA 79-178 for the purpose of obtaining approval to market its Testosterone Gel 1% product did not and does not infringe any valid and enforceable claim of the '606 patent under 35 U.S.C. §271(e)(2), nor would the manufacture, use, sale, offer of sale in and/or importation into the United States of USL's proposed Testosterone Gel 1% infringe any valid and enforceable claim of the '606 patent. USL's making, using, offering to sell, selling, and/or importing Testosterone Gel 1% does not and will not infringe, induce infringement or contribute to infringement by others of any claim of the '606 patent, even under the broadest reasonable construction of the claims of the '606 patent. USL cannot literally (either directly or contributorily) infringe any claim of the '606 patent because one of the components recited in each of the claim of the patent is entirely absent from USL's Testosterone Gel 1%. Moreover, USL cannot infringe (either directly or contributorily) under the doctrine of equivalents. Evidence in the specification and the statements made during prosecution demonstrate that the patentee recognized that the claimed invention's advancement over the prior art was the inclusion of the specific enhancer oxacyclohexadecan-2-one. The USL formulations are not within scope of the claimed invention, but instead, include only components found in the prior art acknowledged by the patentee during patent prosecution. If any claim of the '606 patent were to be interpreted more broadly than this broadest construction, the claim would be invalid. As such, this count is amenable to summary judgment, even prior to a determination on claim construction.

45. USL is entitled to a declaration that the manufacture, use, sale, offer of sale and/or importation into the United States of the Testosterone Gel 1% product would not infringe any valid and enforceable claims of the '606 patent.

COUNT IV

**DECLARATORY JUDGEMENT OF INVALIDITY
OF U.S. PATENT NO. 7,608,606**

46. USL hereby restates and realleges the allegations set forth in Paragraphs 1-45 above and incorporates them by reference.

47. The '606 patent is invalid for failure to meet one or more of the requirements of patentability under 35 U.S.C. §101, *et seq.*, including, but not limited to, 35 U.S.C. §§ 102 and 103.

48. USL is entitled to a declaratory judgment that the claims of the '606 patent are invalid.

COUNT V

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 7,608,607**

49. USL hereby restates and realleges the allegations set forth in Paragraphs 1-48 above and incorporates them by reference.

50. A case or controversy exists between USL and Defendants concerning the non-infringement of the '607 patent requiring a declaration of rights by this Court.

51. USL's submission of ANDA 79-178 for the purpose of obtaining approval to market its Testosterone Gel 1% product did not and does not infringe any valid and enforceable

claim of the '607 patent under 35 U.S.C. §271(e)(2), nor would the manufacture, use, sale, offer of sale in and/or importation into the United States of USL's proposed Testosterone Gel 1% infringe any valid and enforceable claim of the '607 patent. USL's making, using, offering to sell, selling, and/or importing Testosterone Gel 1% does not and will not infringe, induce infringement or contribute to infringement by others of any claim of the '607 patent, even under the broadest reasonable construction of the claims of the '607 patent. USL cannot literally (either directly or contributorily) infringe any claim of the '607 patent because one of the components recited in each of the claim of the patent is entirely absent from USL's Testosterone Gel 1%. Moreover, USL cannot infringe (either directly or contributorily) under the doctrine of equivalents. Evidence in the specification and the statements made during prosecution demonstrate that the patentee recognized that the claimed invention's advancement over the prior art was the inclusion of the specific enhancer oxacyclohexadecan-2-one. The USL formulations are not within scope of the claimed invention, but instead, include only components found in the prior art acknowledged by the patentee during patent prosecution. If any claim of the '607 patent were to be interpreted more broadly than this broadest construction, the claim would be invalid. As such, this count is amenable to summary judgment, even prior to a determination on claim construction.

52. USL is entitled to a declaration that the manufacture, use, sale, offer of sale and/or importation into the United States of the Testosterone Gel 1% product would not infringe any valid and enforceable claims of the '607 patent.

COUNT VI

**DECLARATORY JUDGEMENT OF INVALIDITY
OF U.S. PATENT NO. 7,608,607**

53. USL hereby restates and realleges the allegations set forth in Paragraphs 1-52 above and incorporates them by reference.

54. The '607 patent is invalid for failure to meet one or more of the requirements of patentability under 35 U.S.C. §101, *et seq.*, including, but not limited to, 35 U.S.C. §§ 102 and 103.

55. USL is entitled to a declaratory judgment that the claims of the '607 patent are invalid.

COUNT VII

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 7,608,608**

56. USL hereby restates and realleges the allegations set forth in Paragraphs 1-55 above and incorporates them by reference.

57. A case or controversy exists between USL and Defendants concerning the non-infringement of the '608 patent requiring a declaration of rights by this Court.

58. USL's submission of ANDA 79-178 for the purpose of obtaining approval to market its Testosterone Gel 1% product did not and does not infringe any valid and enforceable claim of the '608 patent under 35 U.S.C. §271(e)(2), nor would the manufacture, use, sale, offer of sale in and/or importation into the United States of USL's proposed Testosterone Gel 1% infringe any valid and enforceable claim of the '608 patent. USL's making, using, offering to

sell, selling, and/or importing Testosterone Gel 1% does not and will not infringe, induce infringement or contribute to infringement by others of any claim of the '608 patent, even under the broadest reasonable construction of the claims of the '608 patent. USL cannot literally (either directly or contributorily) infringe any claim of the '608 patent because one of the components recited in each of the claim of the patent is entirely absent from USL's Testosterone Gel 1%. Moreover, USL cannot infringe (either directly or contributorily) under the doctrine of equivalents. Evidence in the specification and the statements made during prosecution demonstrate that the patentee recognized that the claimed invention's advancement over the prior art was the inclusion of the specific group of macrocyclic enhancers consisting of 3-methylcyclopentadecanone, 9-cycloheptadecen-1-one, cyclohexadecanone, cyclopentadecanone, and oxacyclohexadecan-2-one. The USL formulations are not within scope of the claimed invention, but instead, include only components found in the prior art acknowledged by the patentee during patent prosecution. If any claim of the '608 patent were to be interpreted more broadly than this broadest construction, the claim would be invalid. As such, this claim is amenable to summary judgment, even prior to a determination on claim construction.

59. USL is entitled to a declaration that the manufacture, use, sale, offer of sale and/or importation into the United States of the Testosterone Gel 1% product would not infringe any valid and enforceable claims of the '608 patent.

COUNT VIII

**DECLARATORY JUDGEMENT OF INVALIDITY
OF U.S. PATENT NO. 7,608,608**

60. USL hereby restates and realleges the allegations set forth in Paragraphs 1-59 above and incorporates them by reference.

61. The '608 patent is invalid for failure to meet one or more of the requirements of patentability under 35 U.S.C. §101, *et seq.*, including, but not limited to, 35 U.S.C. §§ 102 and 103.

62. USL is entitled to a declaratory judgment that the claims of the '608 patent are invalid.

COUNT IX

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 7,608,609**

63. USL hereby restates and realleges the allegations set forth in Paragraphs 1-62 above and incorporates them by reference.

64. A case or controversy exists between USL and Defendants concerning the non-infringement of the '609 patent requiring a declaration of rights by this Court.

65. USL's submission of ANDA 79-178 for the purpose of obtaining approval to market its Testosterone Gel 1% product did not and does not infringe any valid and enforceable claim of the '609 patent under 35 U.S.C. §271(e)(2), nor would the manufacture, use, sale, offer of sale in and/or importation into the United States of USL's proposed Testosterone Gel 1% infringe any valid and enforceable claim of the '609 patent. USL's making, using, offering to sell, selling, and/or importing Testosterone Gel 1% does not and will not infringe, induce infringement or contribute to infringement by others of any claim of the '609 patent, even under the broadest reasonable construction of the claims of the '609 patent. USL cannot literally (either directly or contributorily) infringe any claim of the '609 patent because one of the components recited in each of the claim of the patent is entirely absent from USL's Testosterone

Gel 1%. Moreover, USL cannot infringe (either directly or contributorily) under the doctrine of equivalents. Evidence in the specification and the statements made during prosecution demonstrate that the patentee recognized that the claimed invention's advancement over the prior art was the inclusion of the specific enhancer oxacyclohexadecan-2-one. The USL formulations are not within scope of the claimed invention, but instead, include only components found in the prior art acknowledged by the patentee during patent prosecution. If any claim of the '609 patent were to be interpreted more broadly than this broadest construction, the claim would be invalid. As such, this count is amenable to summary judgment, even prior to a determination on claim construction.

66. USL is entitled to a declaration that the manufacture, use, sale, offer of sale and/or importation into the United States of the Testosterone Gel 1% product would not infringe any valid and enforceable claims of the '609 patent.

COUNT X

DECLARATORY JUDGEMENT OF INVALIDITY
OF U.S. PATENT NO. 7,608,609

67. USL hereby restates and realleges the allegations set forth in Paragraphs 1-66 above and incorporates them by reference.

68. The '609 patent is invalid for failure to meet one or more of the requirements of patentability under 35 U.S.C. §101, *et seq.*, including, but not limited to, 35 U.S.C. §§ 102 and 103.

69. USL is entitled to a declaratory judgment that the claims of the '609 patent are invalid.

COUNT XI

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 7,608,610

70. USL hereby restates and realleges the allegations set forth in Paragraphs 1-69 above and incorporates them by reference.

71. A case or controversy exists between USL and Defendants concerning the non-infringement of the '610 patent requiring a declaration of rights by this Court.

72. USL's submission of ANDA 79-178 for the purpose of obtaining approval to market its Testosterone Gel 1% product did not and does not infringe any valid and enforceable claim of the '610 patent under 35 U.S.C. §271(e)(2), nor would the manufacture, use, sale, offer of sale in and/or importation into the United States of USL's proposed Testosterone Gel 1% infringe any valid and enforceable claim of the '610 patent. USL's making, using, offering to sell, selling, and/or importing Testosterone Gel 1% does not and will not infringe, induce infringement or contribute to infringement by others of any claim of the '610 patent, even under the broadest reasonable construction of the claims of the '610 patent. USL cannot literally (either directly or contributorily) infringe any claim of the '610 patent because one of the components recited in each of the claim of the patent is entirely absent from USL's Testosterone Gel 1%. Moreover, USL cannot infringe (either directly or contributorily) under the doctrine of equivalents. Evidence in the specification and the statements made during prosecution demonstrate that the patentee recognized that the claimed invention's advancement over the prior art was the inclusion of the specific group of macrocyclic enhancers consisting of 3-methylcyclopentadecanone, 9-cycloheptadecen-1-one, cyclohexadecanone, cyclopentadecanone, and oxacyclohexadecan-2-one. The USL formulations are not within scope of the claimed

invention, but instead, include only components found in the prior art acknowledged by the patentee during patent prosecution. If any claim of the '610 patent were to be interpreted more broadly than this broadest construction, the claim would be invalid. As such, this count is amenable to summary judgment, even prior to a determination on claim construction.

73. USL is entitled to a declaration that the manufacture, use, sale, offer of sale and/or importation into the United States of the Testosterone Gel 1% product would not infringe any valid and enforceable claims of the '610 patent.

COUNT XII

**DECLARATORY JUDGEMENT OF INVALIDITY
OF U.S. PATENT NO. 7,608,610**

74. USL hereby restates and realleges the allegations set forth in Paragraphs 1-73 above and incorporates them by reference.

75. The '610 patent is invalid for failure to meet one or more of the requirements of patentability under 35 U.S.C. §101, *et seq.*, including, but not limited to, 35 U.S.C. §§ 102 and 103.

76. USL is entitled to a declaratory judgment that the claims of the '610 patent are invalid.

COUNT XIII

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 7,935,690**

77. USL hereby restates and realleges the allegations set forth in Paragraphs 1-76 above and incorporates them by reference.

78. A case or controversy exists between USL and Defendants concerning the non-infringement of the '690 patent requiring a declaration of rights by this Court.

79. USL's submission of ANDA 79-178 for the purpose of obtaining approval to market its Testosterone Gel 1% product did not and does not infringe any valid and enforceable claim of the '690 patent under 35 U.S.C. §271(e)(2), nor would the manufacture, use, sale, offer of sale in and/or importation into the United States of USL's proposed Testosterone Gel 1% infringe any valid and enforceable claim of the '690 patent. USL's making, using, offering to sell, selling, and/or importing Testosterone Gel 1% does not and will not infringe, induce infringement or contribute to infringement by others of any claim of the '690 patent, even under the broadest reasonable construction of the claims of the '690 patent. USL cannot literally (either directly or contributorily) infringe any claim of the '690 patent because one of the components recited in each of the claim of the patent is entirely absent from USL's Testosterone Gel 1%. Moreover, USL cannot infringe (either directly or contributorily) under the doctrine of equivalents. Evidence in the specification and the statements made during prosecution demonstrate that the patentee recognized that the claimed invention's advancement over the prior art was the inclusion of the specific group of macrocyclic enhancers consisting of 3-methylcyclopentadecanone, 9-cycloheptadecen-1-one, cyclohexadecanone, cyclopentadecanone, and oxacyclohexadecan-2-one. The USL formulations are not within scope of the claimed invention, but instead, include only components found in the prior art acknowledged by the patentee during patent prosecution. If any claim of the '690 patent were to be interpreted more broadly than this broadest construction, the claim would be invalid. As such, this count is amenable to summary judgment, even prior to a determination on claim construction.

80. USL is entitled to a declaration that the manufacture, use, sale, offer of sale and/or importation into the United States of the Testosterone Gel 1% product would not infringe any valid and enforceable claims of the '690 patent.

COUNT XVI

**DECLARATORY JUDGEMENT OF INVALIDITY
OF U.S. PATENT NO. 7,935,690**

81. USL hereby restates and realleges the allegations set forth in Paragraphs 1-80 above and incorporates them by reference.

82. The '690 patent is invalid for failure to meet one or more of the requirements of patentability under 35 U.S.C. §101, *et seq.*, including, but not limited to, 35 U.S.C. §§ 102 and 103.

83. USL is entitled to a declaratory judgment that the claims of the '690 patent are invalid.

COUNT XV

**DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF
U.S. PATENT NO. 8,063,029**

84. USL hereby restates and realleges the allegations set forth in Paragraphs 1-83 above and incorporates them by reference.

85. A case or controversy exists between USL and Defendants concerning the non-infringement of the '029 patent requiring a declaration of rights by this Court.

86. USL's submission of ANDA 79-178 for the purpose of obtaining approval to market its Testosterone Gel 1% product did not and does not infringe any valid and enforceable

claim of the '029 patent under 35 U.S.C. §271(e)(2), nor would the manufacture, use, sale, offer of sale in and/or importation into the United States of USL's proposed Testosterone Gel 1% infringe any valid and enforceable claim of the '029 patent. USL's making, using, offering to sell, selling, and/or importing Testosterone Gel 1% does not and will not infringe, induce infringement or contribute to infringement by others of any claim of the '029 patent, even under the broadest reasonable construction of the claims of the '029 patent. USL cannot literally (either directly or contributorily) infringe any claim of the '029 patent because one of the components recited in each of the claim of the patent is entirely absent from USL's Testosterone Gel 1%. Moreover, USL cannot infringe (either directly or contributorily) under the doctrine of equivalents. Evidence in the specification and the statements made during prosecution demonstrate that the patentee recognized that the claimed invention's advancement over the prior art was the inclusion of the specific group of enhancers consisting of 3-methylcyclopentadecanone, 9-cycloheptadecen-1-one, cyclohexadecanone, cyclopentadecanone, and oxacyclohexadecan-2-one. The USL formulations are not within scope of the claimed invention, but instead, include only components found in the prior art acknowledged by the patentee during patent prosecution. If any claim of the '029 patent were to be interpreted more broadly than this broadest construction, the claim would be invalid. As such, this count is amenable to summary judgment, even prior to a determination on claim construction.

87. USL is entitled to a declaration that the manufacture, use, sale, offer of sale and/or importation into the United States of the Testosterone Gel 1% product would not infringe any valid and enforceable claims of the '029 patent.

COUNT XVI

DECLARATORY JUDGEMENT OF INVALIDITY
OF U.S. PATENT NO. 8,063,029

88. USL hereby restates and realleges the allegations set forth in Paragraphs 1-87 above and incorporates them by reference.

89. The '029 patent is invalid for failure to meet one or more of the requirements of patentability under 35 U.S.C. §101, *et seq.*, including, but not limited to, 35 U.S.C. §§ 102 and 103.

90. USL is entitled to a declaratory judgment that the claims of the '029 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, USL prays this Court:

- a. Declare that no valid and enforceable claim of the '605 patent, the '606 patent, the '607 patent, the '608 patent, the '609 patent, the '610 patent, the '690 patent, and the '029 patent has been infringed;
- b. Declare that the claims of the '605 patent, the '606 patent, the '607 patent, the '608 patent, the '609 patent, the '610 patent, the '690 patent, and the '029 patent are invalid and/or unenforceable;
- c. Permanently enjoin each Defendant, and its respective agents, servants, officers, directors, employees, and all persons acting in concert with it, directly or indirectly, from asserting or otherwise seeking to enforce the '605 patent, the '606 patent, the '607 patent, the '608 patent, the '609 patent, the '610 patent, the '690 patent, and the '029 patent against USL or its proposed Testosterone Gel 1% product;
- d. Declare that this case is an exceptional case under 35 U.S.C. § 285 and awarding USL its attorney's fees, costs, and expenses; and
- e. Award USL any further additional relief as the Court may deem just, proper and equitable.

DATED: September 10, 2012

Respectfully submitted,

By: /s/ Hillel Parness

Hillel I Parness

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, the following action filed in this District involves the validity and/or infringement of the patents recited herein:

Auxilium Pharmaceuticals, Inc. v. Watson Laboratories, Inc. (NV) et al., Civ. Action No. 2:12-cv-03084-JLL-MAH (D. N.J. filed May 23, 2012).

I hereby certify, to the best of my knowledge, the following action involves the similar parties and the same ANDA, however, the action involves a different patent than those for which USL is seeking declaration herein:

Auxilium Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., Civ. Action No. 08-908-SLR (D. Del. filed December 4, 2008).

DATED: September 10, 2012

Respectfully submitted,

By: /s/ Hillel Parness

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